UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,129	03/19/2004	Debasis Bagchi	31174/30019	8914

4743 7590 01/05/2009

MARSHALL, GERSTEIN & BORUN LLP
233 S. WACKER DRIVE, SUITE 6300
SEARS TOWER
CHICAGO, IL 60606

EXAMINER	
POLANSKY, GREGG	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
01/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/805,129	BAGCHI ET AL.	
	Examiner	Art Unit	
	GREGG POLANSKY	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,9-11,18,25,32,36-43,51-53,60,67,74,78-85 and 93-106* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,9-11,18,25,32,36-43,51-53,60,67,74,78-85 and 93-106* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Applicants' submission, filed 9/04/2008, amends Claims 85, 95-97, 103, and 106, and presents arguments in response to the Office Action mailed 3/04/2008.

2. Claims 1, 9-11, 18, 25, 32, 36-43, 51-53, 60, 67, 74, 78-85 and 93-106 are pending and are presently under consideration.

Applicants' amendments and arguments have been fully considered and are persuasive in part. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 9-11,18, 25, 43, 51-53, 60, 67, 85 and 93-97 are rejected under 35 U.S.C. 102(e) as being anticipated by Bhaskaran et al., (U.S. 2003/0207942).

Bhaskaran teaches compositions comprising combined potassium-calcium salts of hydroxycitric acid in amounts ranging from about 15 mg to about 3 gm administered up to three times per day, and methods of reducing body weight using said compositions. See Example 3, page 4; page 6, paragraph [0058]; and page 7, claim 24. The reference also teaches hydroxycitric acid is derived from the rind of the fruits of *Garcinia cambogia.* See Abstract.

Since Bhaskaran teaches the same compound administered at the same amount as the instant claims, the functionality (i.e., decreasing ghrelin levels) would also be the same. See *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) that discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the Applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention").

It is noted that Claims 85 and 93-97 are drawn to a composition of hydroxycitric acid. The intended use of the compositions confers no patentable weight to the claims. *In re Hack*, 114 USPQ 161. A recitation of the intended use of the claimed composition must result in a structural difference between the claimed composition and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

5. Claims 1, 9, 10, 43, 51, 52, 85, 93, 94, 105 and 106 are rejected under 35 U.S.C. 102(b) as being anticipated by Balasubramanyam et al. (U.S. Patent No. 6,160,172).

Balasubramanyam et al. teach double metal salts of group IA and IIA of hydroxycitric acid which are useful in beverage and various food product formulations without affecting their flavor and properties. The group IA metals include potassium and the group IIA metals include calcium (as required by instant Claims 105-106). See column 1, 1st paragraph and column 2, lines 23-27. The reference teaches hydroxycitric acid is derived from the rind of the fruits of *Garcinia* species, as, for example, *Garcinia cambogia*. See column 1, 2nd paragraph. Balasubramanyam et al. also teach hydroxycitric acid useful in weight reduction. See column 1, 3rd paragraph.

It is noted that Claims 85, 93, and 94 are drawn to a composition of hydroxycitric acid. The intended use of the compositions confers no patentable weight to the claims. *In re Hack*, 114 USPQ 161 and *supra*.

As discussed in the anticipation rejection to Bhaskaran (*supra)*, administration of a composition comprising hydroxycitric acid and it salts as taught by Balasubramanyam et al. would naturally have the same functionality (i.e., decreasing ghrelin levels) as the

instantly claimed compositions and methods. See *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594).

Applicants argue '[t]he anticipation rejections over Bhaskaran and Balasubramanyam should be withdrawn because decreased ghrelin levels cannot be considered inherent in all compounds that are associated with weight reduction". Applicants argue that although the prior art discloses that hydroxycitric acid is administered to aid in weight reduction, "there is nothing in the prior art that teaches HCA decreases ghrelin levels".

Instant Claims 85, 93-97, 105, and 106 are drawn to a composition and not a method of treatment. As presented *supra*, the intended use of compositions confers no patentable weight to the claims. Further, whereas both cited references teach the administration of the same composition as is instantly claimed (i.e., comprising hydroxycitric acid), including administration of the composition to individuals in need of weight reduction, it would naturally follow that said composition would have the same effect on ghrelin levels as the instantly claimed composition, as used by the instant methods.

Applicants presented additional arguments, which were repeated from their response filed 1/15/2008. The Office responded to these arguments in the Office Action mailed 3/04/2008.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 9-11, 18, 25, 32, 36-43, 51-53, 60, 67, 74, 78-85 and 93-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raju, G. (WO 99/03464), in view of Policapelli et al. (U.S. Patent No. 5,612,039), Allen, A. (U.S. Patent No. 5,480,657), Alviar et al. (U.S. Patent No. 6,413,545), and Balasubramanyam et al. (U.S. Patent No. 6,160,172).

Raju teaches hydroxycitric acid compositions that comprise both calcium and potassium for use in the reduction of body weight. See the Abstract. The source of the hydroxycitric acid is found in the rind of the fruits of *Garcinia* species, as, for example, *Garcinia cambogia*. See page 1, lines 21-23, as well as page 3, lines 21-24. As

required by instant claims 11, 18, 25, 53, 60, 67, 95-97, a suitable dosage ranges from about 15 to about 3000 mg of hydroxycitric acid up to three times per day (15 to 9000 mg hydroxycitric acid per day). See page 10, lines 18-24.

Policappelli teaches the administration of dietary compositions for weight loss comprising *Garcinia cambogia* in addition to *Gymnema sylvestre* extract and chromium bound to nicotinate. See claim 8, column 10, where, as required by instant claims 32 and 74, the administration of the composition is three times daily before a meal.

Allen teaches compositions for treatment of weight gain comprising caffeine, as for example, in tea, in addition niacin-bound chromium. See the Abstract. As required by instant claims 83, 84, 103 and 104, the chromium is present in an amount of approximately 5 mcg to 500 mcg. See lines 1-2, column 9.

Alviar teaches compositions for managing body weight comprising effective amounts of *Garcinia cambogia* extract and *Gymnema sylvestre* extract. As required by instant claims 41, 42, 83, 84, 103 and 104, the daily effective amount of Gymnema *sylvestre* extract is from about 27 to about 293 mg. See column 3, lines 58-62. The open language of the present claims allows for the inclusion of any number of additional active agents.

The teachings of Balasubramanyam et al. are presented *supra*.

Further, it is noted that instant Claims 85 and 93-106 are directed to compositions, not methods. As discussed *supra*, intended use of the compositions confers no patentable weight to the claims.

As discussed *supra*, the hydroxycitric acid compositions taught and suggested by the prior art would have the same functionality (e.g., decreasing ghrelin levels) of the instantly claimed hydroxycitric acid compositions. See MPEP 2112(1) "[T}he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer.' *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed.Cir. 1999). Thus, claiming a new use, new function or unknown property which is, absent factual evidence to the contrary, present in the prior art does not necessarily make the claim patentable. *In re Best,* 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)."

With respect to claimed dosage ranges of the active agents in the instant compositions and methods of use, it is not inventive to discover the optimum or workable ranges by routine experimentation when general conditions of a claim are disclosed in the prior art. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955) and MPEP 2144.05(11). The determination of the optimum dosage regimen to employ with the presently claimed active agents would have been a matter well within the purview of one of ordinary skill in the art. Such determination would have been made in accordance with a variety of factors. These would have included such factors as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is

administered a part of a drug combination. Thus, in the absence of evidence to the contrary, the currently claimed specific dosage amounts and dosage regimens are not seen to be inconsistent with the dosages that would have been determined by one of ordinary skill in the art.

In view of the combined references set forth *supra*, one skilled in the art would have been motivated to prepare a composition comprising hydroxycitric acid, optionally bound to calcium and potassium or as a dual salt of calcium and potassium, that is derived from the plant *Garcinia cambogia*, optionally further comprising gymnemic acid, tea, niacin-bound chromium and caffeine in methods to reduce body weight. Such would have been obvious in the absence of evidence to the contrary because each of the claimed components in Applicants' compositions is disclosed in the prior art for the purpose of reducing body weight.

Applicants argue that none of the references cited teach hydroxycitric acid decreases ghrelin levels. Applicants' assert that identification of hydroxycitric acid as a regulator of ghrelin levels was made by the Office "only in hindsight based on Applicants' own disclosure"

As discussed above, since the prior art teaches the same hydroxycitric acid compositions and at the same doses as instantly claimed, it would be expected to have the same effect on ghrelin levels as the instantly claimed compositions. Claiming a new use, new function or unknown property which is, absent factual evidence to the contrary, present in the prior art does not necessarily make the claims patentable.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. In the last Office Action claims 85 and 93-104 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-27, 29, and 31-41 of copending Application No. 09/463024. Although the conflicting claims are not identical, they are not patentably distinct from each other because the co-pending application is drawn to compositions comprising a salt of hydroxycitric acid wherein the claimed concentration ranges are encompassed in the present claim language. The open language of the claims allows for the inclusion of additional active agents in the compositions.

Applicants elect to hold this issue in abeyance. The rejection of Claims 85 and 93-104 on the ground of nonstatutory obviousness-type double patenting is maintained.

Conclusion

11. Claims 1, 9-11, 18, 25, 32, 36-43, 51-53, 60, 67, 74, 78-85 and 93-106 are rejected

12. No claims are allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGG POLANSKY whose telephone number is (571)272-9070. The examiner can normally be reached on Mon-Thur 9:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregg Polansky/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614